



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

g1461d

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

June 28, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 69

John C. Gale, Chief Executive Officer
Rajiv Lall, President
Vets Plus, Inc.
102 Third Avenue East
Knapp, Wisconsin 54749

Dear Mssrs. Gale and Lall:

An investigator from the Minneapolis District office of the U.S. Food and Drug Administration (FDA) conducted an inspection of your veterinary drug and nutritional supplement manufacturing facility on March 7 and 13, 2001.

During the inspection the investigator obtained copies of four of your firm's product catalogs as well as labels for five of the products that your firm manufactures and markets either under your own Vets Plus, Horses Prefer, Pets Prefer or DVM Formula labels, or that are private labeled for one of more of your customer firms.

Our review of the labels as well as the product catalogs for AGRI PLUS Calcium Drench, Vets Plus Cal-C-Fresh, AGRI PLUS CMPK with D3 Drench, Vets Plus Keto-Nia Fresh and HORSES Prefer BIO-HOOF found that they contain therapeutic or structure-function claims that would cause all five products to be animal drugs as defined under Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). All five products are also new animal drugs as defined under Section 201(v) of the Act. Your firm has not submitted nor received approval for new animal drug applications for any of the five products in accordance with Section 512 of the Act. The fact that your firm is manufacturing and marketing unapproved new animal drugs without approval causes those products to be adulterated under, and in violation of, Section 501(a)(5) of the Act.

We have reviewed claims made in your four product catalogs. Those claims cause numerous products that your firm markets and promotes to be misbranded drugs

Page Two

John C. Gale and Rajiv Lall
June 28, 2001

under Section 502(f)(1) of the Act since those products lack adequate directions for use for the claims, conditions or purposes for which they are intended. For many of these products, adequate directions for use may not be known since the safety and efficiency of these products for these conditions has not been demonstrated.

In addition, your firm has failed to list any of your products with the Center for Veterinary Medicine (CVM) in accordance with Section 510 of the Act. Failure to list these products as required causes them to be misbranded under, and in violation of, Section 502(o) of the Act.

The current inspection of your veterinary drug manufacturing facility found that it was not being operated in accordance with the Current Good Manufacturing Practices for Finished Pharmaceuticals (CGMPs) found under Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Failure to comply with the CGMPs causes products manufactured under those conditions to be adulterated under Section 501(a)(2)(B) of the Act.

The products specifically referenced in this letter do not constitute the only products manufactured and marketed by your firm that we consider to be new animal drugs without approval. You should immediately review your entire line of products to determine which products are unapproved new animal drugs and whose labels/labeling contain either direct or implied therapeutic or structure-function claims that cause those products to be drugs under Section 201(g) of the Act and unapproved new animal drugs under Section 201(v) of the Act. We also wish to point out that promotional efforts on the internet can help establish the intended uses of the products. Your firm's web sites contain numerous promotional statements and claims for the four lines of products marketed by your firm that help establish that your firm's products are clearly intended to be used as animal drugs. We also wish to point out that direct fed microbial products (probiotics) such as those manufactured and marketed by your firm can be regulated as either foods or drugs depending on the claims made. You may want to refer to our Compliance Policy Guide (CPG) 689.100 on Direct Fed Microbials which can be found on the CVM web site at: <http://www.fda.gov>. The labeling for the direct fed microbial products (probiotics) manufactured and marketed by your firm contain numerous therapeutic and/or structure-function claims that cause them to be regarded as animal drugs and, since no approval exists, as unapproved new animal drugs. You will need to take whatever steps are necessary to correct the status of your firm's products as unapproved new animal drugs. Such steps can include changes in labeling claims or cessation of marketing.

You should not assume that the deficiencies listed on the form FDA-483, Inspectional Observations, issued to your firm at the close of the current inspection on March 13, 2001, constitute a complete list of GMP problems at your firm. You should take immediate steps to review all the procedures, practices and

Page Three


John C. Gale and Rajiv Lall
June 28, 2001

controls in place at your firm as well as any records maintained to determine if they are adequate within the requirements of the Current Good Manufacturing Practices for Drugs (CGMPs) found under 21 CFR 211 and to take whatever steps are necessary to make corrections.

You should take prompt action to correct all violations and deficiencies referred to in this letter. Failure to promptly correct the violations and deficiencies may result in regulatory action such as seizure or injunction without further notice. This letter is official notification from the FDA that we expect all of your facilities and operations to be in compliance with the laws and regulations enforced by the Agency.

We request that you reply in writing within 15 days of your receipt of this letter stating what actions your firm has taken or will take to bring about correction and compliance. You may direct your reply to the attention of Compliance Officer Carrie Hoffman at the address shown on the letterhead.

Sincerely,


James A. Rahto
Director
Minneapolis District

CAH/ccl
